

Monovettes LH (Blood gas)

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

For near-patient (POCT), immediate determination of blood gases, pH or electrolytes.

Uses advised against

See instructions for use - SARSTEDT S-Monovette® Blood collection system at www.sarstedt.com.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: SARSTEDT AG & Co. KG
Street: Sarstedtstraße 1
Place: D-51588 Nümbrecht
Post-office box: 1220
D-51582 Nümbrecht
Telephone: +49 (0)2293 / 305 - 0
Telefax: +49 (0)2293 / 305 - 2470
e-mail: info@sarstedt.com
Contact person: Dr. Daniel Will
Telephone: +49 (0)2293 / 305 - 4500
Jochen Hoffmann
e-mail: sicherheitsdatenblatt@sarstedt.com
Internet: www.sarstedt.com
Responsible Department: R & D Center

Supplier

Company name: SARSTEDT Ltd.
Street: Optimus Way, Optimus Point
Place: GB-LE3 8JR Leicester
Telephone: +44 (0) 116 235 9023
Telefax: +44 (0) 116 236 6099
e-mail: info.gb@sarstedt.com
Internet: www.sarstedt.com

1.4. Emergency telephone number:

Call NHS 111 or a doctor (public). NPIS: 0344 892 0111 (healthcare professionals).

Further Information

All information in this safety data sheet refers to the unused product and its preparation.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Respiratory or skin sensitisation: Resp. Sens. 1

Respiratory or skin sensitisation: Skin Sens. 1

Hazard Statements:

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Lithium heparin

Calcium heparin

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Signal word: Danger

Pictograms:



Hazard statements

- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P302+P352 IF ON SKIN: Wash with plenty of Water.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Additional advice on labelling

none

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

The Monovette® contains a calcium-balanced heparin solution (50 I.U./mL nominal volume).

Hazardous components

CAS No	Chemical name	Quantity
	EC No Index No REACH No	
	GHS Classification	
9045-22-1	Lithium heparin	5 - < 10 %
	232-681-7	
	Acute Tox. 4, Resp. Sens. 1, Skin Sens. 1; H302 H334 H317	
37270-89-6	Calcium heparin	1 - < 5 %
	Acute Tox. 4, Resp. Sens. 1, Skin Sens. 1; H302 H334 H317	

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
9045-22-1	232-681-7	Lithium heparin	5 - < 10 %
		oral: LD50 = 1950 mg/kg	
37270-89-6		Calcium heparin	1 - < 5 %
		oral: LD50 = 1950 mg/kg	

SECTION 4: First aid measures

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4.1. Description of first aid measures

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

In case of fire, the smoke may contain, in addition to the base material, combustion products with not definable toxic and / or irritant compositions. Combustion products may i.a. contain: carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

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7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective gloves during blood collection and if handling potentially infectious material. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

For near-patient (POCT), immediate determination of blood gases, pH or electrolytes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Wear suitable protective gloves during blood collection and if handling potentially infectious material.

Skin protection

Use of protective clothing.

Respiratory protection

Not required if used as intended.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:	colourless	
Odour:	characteristic	
pH-Value:		not determined
Changes in the physical state		
Melting point:		not determined

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Boiling point or initial boiling point and boiling range: not determined

Flash point: not determined

Flammability

Solid/liquid: not applicable

Gas: not applicable

Explosive properties

No data available

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature: not determined

Self-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

No data available

Vapour pressure: not determined

Density: not determined

Water solubility: Preparation soluble

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Relative vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Exposure route	Dose	Species	Source	Method	
9045-22-1	Lithium heparin					
	oral	LD50 1950 mg/kg	Rat	ChemIDplus - Database		
37270-89-6	Calcium heparin					
	oral	LD50 1950 mg/kg	Rat	ChemIDplus - Database		

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause allergy or asthma symptoms or breathing difficulties if inhaled . (Lithium heparin; Calcium heparin)
 May cause an allergic skin reaction. (Lithium heparin; Calcium heparin)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

11.2. Information on other hazards

Endocrine disrupting properties

No information available.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Endocrine disrupting properties

The product has not been tested.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 1 - slightly hazardous to water

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Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

First issue.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
 REACH: Registration, Evaluation and Authorization of Chemicals
 GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
 UN: United Nations
 CAS: Chemical Abstracts Service
 DNEL: Derived No Effect Level
 DMEL: Derived Minimal Effect Level
 PNEC: Predicted No Effect Concentration
 ATE: Acute toxicity estimate
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%
 LL50: Lethal loading, 50%
 EL50: Effect loading, 50%
 EC50: Effective Concentration 50%
 ErC50: Effective Concentration 50%, growth rate
 NOEC: No Observed Effect Concentration
 BCF: Bio-concentration factor
 PBT: persistent, bioaccumulative, toxic
 vPvB: very persistent, very bioaccumulative
 ADR: Accord européen sur le transport des marchandises dangereuses par Route
 (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 RID: Regulations concerning the international carriage of dangerous goods by rail
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation
 intérieures)
 IMDG: International Maritime Code for Dangerous Goods
 EmS: Emergency Schedules
 MFAG: Medical First Aid Guide
 IATA: International Air Transport Association
 ICAO: International Civil Aviation Organization
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships
 IBC: Intermediate Bulk Container
 SVHC: Substance of Very High Concern
 For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Resp. Sens. 1; H334	Calculation method
Skin Sens. 1; H317	Calculation method

Relevant H and EUH statements (number and full text)

H302 Harmful if swallowed.
 H317 May cause an allergic skin reaction.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of

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product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)